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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,187	03/05/2001	Christina M. Grozinger	HUV-037.01	3390

25181 7590 06/30/2003

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/800,187

Applicant(s)

GROZINGER ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this c mmunication appears on th c ver sheet with the correspondenc address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4-12,15,16,25,26 and 29-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,13,14,17-24,27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-77 are pending.

### ***Election/Restriction***

Applicant's election with traverse of Group III, drawn to a DNA encoding SEQ ID NO:6, in Paper No. 11 filed May 27, 2003 is acknowledged. The traversal is on the ground(s) that "search and examination of a DNA encoding SEQ ID NO:6 polypeptide would also entail a search and examination of the SEQ ID NO:6 polypeptide sequence, posing no serious burden. Accordingly, Applicants respectfully request examination of the Group XII claims, drawn to a polypeptide of SEQ ID NO:6 simultaneously" (Response, paragraph bridging pages 1-2). This is not found persuasive because as stated in the Restriction requirement mailed April 24, 2003, a DNA and a polypeptide are different compounds each with its own chemical structure and function, and they have different utilities. Furthermore, the examination of Group XII would require divergent considerations.

The requirement is still deemed proper and is therefore made FINAL.

The examiner notes that the Restriction requirement contained an inadvertent typographical error in claim numbers. The correct numbers of the claims drawn to a DNA encoding SEQ ID NO:6, are 3, 13, 14, 17, 18-24, 27, 28. These claims are under consideration in the current Office action.

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Claims 1, 2, 4-12, 15, 16, 25, 26 and 29-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups I, II and IV-XIX, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

### ***Specification***

On page 3, lines 8-9, the specification refers to GenBank Accession No. NM\_006044. The examiner is unable to find the sequence with said Accession No.

Clarification is required.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. 37 CFR 1.821(d) requires the use of assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences.

The following are examples of noncompliance where the sequence containing more than ten nucleotides or four amino acids is given without a sequence identifier: Figure 1 or descriptions thereof.

Appropriate correction is required.

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### ***Claim Objections***

Claims 13, 14, 17, 18-24, 27 and 28 are objected to because of the following informalities:

Claims 13, 14, 17, 18-24, 27 and 28 recite "an *HDx* polypeptide". It is suggested that the first time an abbreviation is used in a claim for a term that is not clearly defined in the specification (page 2), that the abbreviated term be written out in full, followed by its abbreviation in parenthesis. For the purposes of the current examination "an *HDx* polypeptide" was construed as a polypeptide having a histone deacetylase activity.

Appropriate correction is required.

Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 18 is drawn to the nucleic acid of claim 17 encoding an *HDx* polypeptide which *HDx* polypeptide has a molecular weight in the range of 40kD to 90kD. Claim 17 is drawn to the nucleic acid encoding an *HDx* polypeptide which *HDx* polypeptide comprises a polypeptide sequence designated in SEQ ID NO:6. Since SEQ ID NO:6 consists of 1215 amino acids, its molecular weight is more than 90kD. The scope of claim 17 does not include fragments of SEQ ID NO:6.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 is drawn to a nucleic acid which hybridizes under stringent conditions to a nucleotide sequence designated in SEQ ID NO:5 and having no functional limitations.

The specification does not contain any disclosure of the structure and function of nucleic acids which hybridize under stringent conditions to a nucleotide sequence designated in SEQ ID NO:5. The genus of nucleic acids that comprise these above nucleic acid molecules is a large variable genus with the potentiality of encoding proteins having many different functions. Therefore, nucleic acids encoding many structurally and functionally unrelated proteins are encompassed within the scope of the claim, including partial sequences. The specification discloses only a single species of the claimed genus, a human nucleic acid of SEQ ID NO:5 encoding an HDx polypeptide of SEQ ID NO:6. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties and fails to

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provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO:5, does not reasonably provide enablement for a nucleic acid that hybridizes to SEQ ID NO:5 and encodes a polypeptide with unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are

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summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

As discussed above, claim 3 is drawn to a nucleic acid which hybridizes under stringent conditions to a nucleotide sequence designated in SEQ ID NO:5 and having no functional limitations. Nucleic acids which hybridize under stringent conditions to SEQ ID NO:5 comprise different nucleic acid molecules encoding *HDx* polypeptides and encoding polypeptides with undisclosed function. While the specification teaches how to use an *HDx* polypeptide, it provides no guidance as to what is the function of other polypeptides encoded by the claimed nucleic acids.

Without knowing the function of a polypeptide one of skill in the art would not have known how to use it and a nucleic acid encoding thereof.

Therefore, one of ordinary skill in the art would require guidance, in order to use a nucleic acid that hybridizes to SEQ ID NO:5 and encodes a polypeptide with unknown function in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.



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Claims 3, 13, 14, 17, 18-24, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "stringent conditions". Said conditions can be defined differently. Depending on the exact conditions, different nucleic acids will hybridize to SEQ ID NO:5 rendering the metes and bounds of the claim unascertainable.

Claims 13, 14, 17, 18-24, 27 and 28 recite "or fragment thereof". From the way the claims are written, it is unclear whether said fragment is an *HDx* polypeptide or just any fragment. For the purposes of this Office action, the former meaning is construed, i.e. a fragment retaining a *HDx* polypeptide activity. The examiner notes that without defining the fragment, it can read on any number of amino acids, e.g., two.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 13, 14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Strom et al. Strom et al. (GenBank accession AJ011972, October 19, 1998) teach nucleic acid of 4099 bp encoding histone deacetylase-like protein (JM21)

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of 1215 amino acids having the amino acid sequence that is 100% identical to SEQ ID NO:6.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strom et al. in view of Schreiber et al.

The teaching of Strom et al. are outlined above.

Schreiber et al. (WO 97/35990, form PTO-1449, reference BA) teach nucleic acids encoding human histone deacetylases, "HDx" genes, and their applications and uses. They teach nucleic acids encoding fusion proteins comprising HDx polypeptides (page 3, lines 29-35, claims 34-35). They teach that a nucleic acid can include a transcriptional regulatory sequence and can be included in a vector and cell (page 4, lines 14-21, claims 37-38). Schreiber et al. teach a method of producing an HDx polypeptide (claim 39). They teach recombinant transfection systems (claims 42-43).

One of ordinary skill in the art at the time the invention was made would have been motivated to make nucleic acids encoding a fusion protein of an HDx polypeptide,

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include a regulatory sequence and to put the construct into a cell as well as to prepare a transfection system as required by claims 19-24, 27 and 28 according to the customary uses of nucleic acids in the art that are specifically taught by Schreiber et al. in relation to nucleic acids encoding *HDx* polypeptides. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because of the high level of knowledge in the field of nucleic acid manipulation and the teachings of Schreiber et al. who successfully applied it to various *HDx* genes.

### **Conclusion**

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

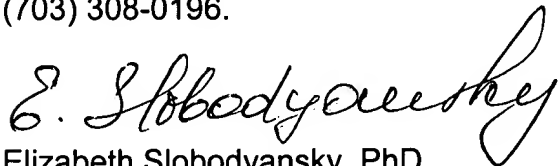
C. Grozinger, C. Hassig and S. Schreiber (April 1999, PNAS, 96,4868-4873, form PTO-1449, reference CD) teach a nucleic acid of SEQ ID NO:5 encoding an *HDx* polypeptide of SEQ ID NO:6. Since the authors are inventors in the instant application, the reference is not a prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in black ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD  
Primary Examiner

June 26, 2003